



K043120

MAR 1 - 2005

Premarket Notification 510(k) Summary
As required by section 807.92
Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and
Uni-Filter

GENERAL COMPANY INFORMATION as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda
86 Pilgrim Road
Needham, MA 02492 USA
Tel: 781-449-8685
Fax: 781-433-1344

NAME OF CONTACT:

Mr. Joel Kent

DATE:

November 8, 2004

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and Uni-Filter

COMMON NAME:

Disposable Bacterial/Viral Filter

CLASSIFICATION NAME:

The following Class II classifications appear applicable:

CAH Breathing Circuit Bacterial Filter 868.5260

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL
EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Mini-Filter/S has the following similarities to the Datex-Ohmeda Mini-Filter/S predicate device (K030990). The Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Intersurgical Clear-Guard (K990949).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and Uni-Filter incorporate an electrostatic filter media into a housing made of translucent plastic.

Dimensions and Materials

§ Diameter: Mini-Filter/S 45 mm. Uni-Filter Junior, Uni-Filter/S and Uni-Filter/S angled are 59 mm. Uni-Filter is 80 mm.

§ Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S and Uni-Filter/S angled length: 64 mm. Uni-Filter length: 73 mm.

§ Housing: PP Polypropylene

§ Filter: PP and acrylic fibers

Filtration efficiency:

· Filtration efficiency viral

Mini-Filter/S 99,98%, Uni-Filter Junior, Uni-Filter/S/ angled Uni-Filter/S 99.999%, Uni-Filter 99.9%

· Filtration efficiency against bacteria

Uni-Filter Junior >99.99999%, Uni-Filter/S/angled Uni-Filter/S 99.9999%, Uni-Filter 99.98%

The Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and Uni-Filter are for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators.

They incorporate standard fittings for-

§ 15 mm ID x 22 mm OD fitting to connect to the endotracheal tube or face mask

§ 15 mm OD x 22 mm ID fitting to connect to the breathing circuit Y-piece

§ For the Mini-Filter/S, Uni-Filter/S and Uni-Filter/S angled : A gas sampling port – female luer port with cap to allow sampling of expired CO₂-gases

INTENDED USE as required by 807.92(a)(5)

Intended Use

Indications for use:

Filters can be used to provide filtration for reducing possible cross contamination between patient and equipment. Filters are for use in the hospital, ICU, anesthesia, respiratory therapy, during transport and with resuscitators for filtering particles including bacteria, viruses and dust from CO₂-absorbers. The Uni-Filter/S, angled Uni-Filter/S and Mini-Filter/S can also be used for gas sampling.

The device for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE COMPARED TO THE
PREDICATE DEVICE as required by 807.92(a)(6)

The Mini-Filter/S has the following similarities to the Datex-Ohmeda Mini-Filter/S predicate device (K030990):

- Mini-Filter/S is identical to predicate (K030990) in physical construction and all specifications except labeled resistance as described below.

The Mini-Filter/S has the following differences when compared to the Datex-Ohmeda Mini-Filter/S predicate device:

- The devices differ in labeled breathing resistance
- Labeling is updated to modify the contraindications

The main differences between the Mini-Filter/S and the predicate Datex-Ohmeda Mini-Filter/S (K030990) are due to fact that the updated labeling reflects a more accurate measurement of the breathing resistance values due to updated equipment calibration. There is no material or design change and the product itself is identical. Mini-Filter/S still has lower breathing resistances than Datex-Ohmeda HMEF Mini (K023641).

The main differences between the labeling is that it describes the use of the Mini-Filter/S with nebulizers and active humidification. In this issue Mini-Filter/S is similar to the legally marketed (predicate) Intersurgical Clear-Guard (K990949).

In summary, the Mini-Filter/S, described in this submission is substantially equivalent to the predicate Datex-Ohmeda Mini-Filter/S (K030990).

The Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter are substantially equivalent in safety and effectiveness to the legally marketed (predicate) Intersurgical Clear-Guard (K990949).

The Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter have the following similarities to the Intersurgical Clear-Guard (K990949) predicate devices:

- Have a similar indicated use
- Have the same fundamental scientific technology and use the same operating principle

The Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter have the following differences when compared to the Intersurgical Clear-Guard (K990949) predicate devices:

- The devices differ in Breathing resistance, weight, dead space and shelf life
- Labeling is updated to modify the contraindications
- Filtration efficiency against virus
- Filtration efficiency against bacteria

The main differences between the Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter and the predicate device Intersurgical Clear-Guard (K990949) are due to fact that Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter have better or equal filtration efficiency (except Uni-Filter has lower viral filtration efficiency), smaller weight , smaller dead spaces (except Uni-Filter which is a little bigger filter) and lower resistance than predicate Intersurgical Clear-Guard.

In summary, the Uni-Filter Junior, Uni-Filter/S, angled Uni-Filter/S and Uni-Filter , described in this submission is substantially equivalent to the predicate Intersurgical Clear-Guard (K990949).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

Filter's are normally used and installed by a trained nurse or doctor. Necessary precautions and warnings are stated on the instructions for use (Tab 9).

The Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and Uni-Filter housing are made of medical grade plastic materials commonly known to be suitable for the application. The material used is biocompatible (non-cytotoxic and non-allergic), non-toxic

Disposable Filter's are meant for single patient use only. There is no applicable cleaning, disinfection or sterilization procedures that the operator could use

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled and Uni-Filter as compared to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAR 1 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Joe Kent
Manager, Quality and Regulatory Affairs
GE Healthcare
86 Pilgrim Road
Needham, Massachusetts 02492

Re: K043120
Trade/Device Name: Mini-filter/S, Uni-Filter Junior, Uni-Filter/S
Uni-Filter/S angled and Uni-Filter
Regulation Number: 21 CFR 868.5260
Regulation Name: Breathing Circuit Bacterial Filter
Regulatory Class: II
Product Code: CAH
Dated: February 11, 2005
Received: February 14, 2005

Dear Mr. Kent:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

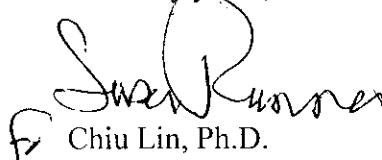
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin", is written over the typed name. To the left of the signature is a small, stylized mark that looks like a capital "F" or a checkmark.

Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Mini-Filter/S, Uni-Filter Junior, Uni-Filter/S, Uni-Filter/S angled
and Uni-Filter

Indications for Use:

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The device for use by qualified medical personnel only.

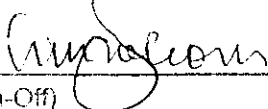
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K043120

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